

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ZS PHARMA, INC. and
ASTRAZENECA PHARMACEUTICALS
LP,

Plaintiffs,

V.

ALKEM LABORATORIES LTD.,

Defendant.

C.A. No. _____

**SUPPLEMENTAL INFORMATION FOR PATENT CASES
INVOLVING AN ABBREVIATED NEW DRUG APPLICATION (ANDA)**

Plaintiffs ZS Pharma, Inc. and AstraZeneca Pharmaceuticals LP (collectively

“Plaintiffs”) hereby provide the information below with respect to the deadlines set forth in 21

U.S.C. § 355(b)(2):

Date Patentee(s) Received Notice:

No Earlier than July 14, 2022

Regulatory Stay Deadline:

No Earlier than November 18, 2025¹

Date of Expiration of Patents:

U.S. Patent No.	Expiration Date
8,877,255	October 22, 2033
9,592,253	October 14, 2035
9,913,860	October 22, 2033
10,300,087	October 14, 2035
10,695,365	October 22, 2033

¹ The stay preventing approval of the proposed generic products expires no earlier than November 18, 2025 (seven and one-half years from the new chemical entity approval on May 18, 2018). *See* 21 U.S.C. § 355(j)(5)(F)(ii).

Dated: August 22, 2022

MCCARTER & ENGLISH, LLP

OF COUNSEL:

Lisa B. Pensabene
Hassen Sayeed
Daniel O'Boyle
James Li
O'MELVENY & MYERS LLP
7 Times Square
New York, New York 10036
(212) 326-2000

/s/ Daniel M. Silver

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

*Attorneys for Plaintiffs ZS Pharma, Inc. and
AstraZeneca Pharmaceuticals LP*